APR 1 2 2001

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Advanced Cardiovascular Systems, Inc.

Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95052

Telephone: 408/845-1067
Fax: 408/845-3743

Contact Person: Saba Modjarrad

Date Prepared: March 7, 2001

Device Trade Name: RX HERCULINK™ PLUS Biliary Stent System

Device Common Name: Biliary Stent

Device Classification Name: Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of RX HERCULINK™ PLUS Biliary Stent System with the 12 mm and 18 mm length stent are substantially equivalent with regard to these features in the predicate device, the RX HERCULINK™ 14 Biliary Stent System with the 13 mm and the 18 mm length stent (K990867, K993588, and K001224).

Device Description:

The RX HERCULINK™ PLUS Biliary Stent System is a balloon-expandable stent pre-mounted onto a rapid exchange (RX) delivery catheter designed to be placed percutaneously into the common bile duct and intended to treat malignant strictures in the biliary tree. The stent and delivery system is for single use only and the biliary stent is a permanent implant.

The RX HERCULINK™ PLUS Biliary Stent is fabricated from a single piece of 316L medical grade stainless steel tubing. The stent is balloon-expandable with an expansion range from 4.0 – 7.0 mm in diameter for the 18 mm length stent and 4.0 – 6.5 mm in diameter for the 12 mm length stent.

The delivery systems for both the 18 mm stent length and 12 mm stent length are available in lengths of 80 cm and 135 cm. The systems are designed as rapid-exchange (RX) catheters with a coaxial design and a balloon at the distal end. The delivery systems for both the 12 mm stent length and the 18 mm

stent length are identical in every aspect but the stent lengths and balloon lengths, 15 mm and 20 mm, respectively. The proximal lumen of the delivery catheter provides for inflation of the balloon with contrast medium. The central distal lumen permits use of a guidewire to facilitate advancement of the catheter tip and through the area to be dilated.

The balloon has radiopaque markers to aid in stent positioning, designed to provide an expandable segment of known diameter and length at specific pressures. An adaption arm on the proximal end of the delivery system provides access to the inflation lumen. It is designed with a luer-lock fitting for connection with an inflation device.

Comparison of the RX HERCULINK™ PLUS Biliary Stent System to the predicate device, the RX HERCULINK™ 14 Biliary Stent system (K990867, K993588, and K001224) indicates that they are substantially equivalent to the predicate with regard to the intended use, materials and design.

Intended Use:

The RX HERCULINK™ PLUS Biliary Stent System is indicated for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices. The design modification of the new biliary stent system compared to that of the predicate biliary stent system is the length of the stent.

Performance Data:

The safety and effectiveness of the RX HERCULINK™ PLUS Biliary Stent System has been demonstrated through data collected from *in vitro* bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Saba Modjarrad
Regulatory Affairs Coordinator
Guidant Corporation
Advanced Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K010684
RX HERCULINK™ PLUS Biliary Stent System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: March 26, 2001
Received: March 27, 2001

Dear Ms. Modjarrad:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010684

Device Name: RX HERCULINK™ PLUS Biliary Stent System

FDA's Statement of the Indications For Use for device:

The RX HERCULINK™ PLUS Biliary Stent System is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010684